

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A stable liposome composition for delivering a pharmaceutical agent, the composition comprising: (a) a suitable aqueous medium; (a) liposomes formed from a suitable phospholipid; (b) at least one pharmaceutical agent being at least partially encapsulated in the liposomes, and being selected from: (i) a lipophilic amine and a pharmaceutically acceptable acid, wherein the pharmaceutically acceptable acid is selected from an organic or inorganic acid, and (ii) a pharmaceutically acceptable organic acid salt of a lipophilic amine, and optionally a pharmaceutically acceptable acid comprising a pharmaceutically acceptable organic acid; wherein the quantity of the pharmaceutically acceptable acid present in the composition is such that the pH of the aqueous medium within said liposome composition is less than or approximately equal to the pK_a of the amino group of the pharmaceutically active lipophilic amine, wherein said liposome composition is autoclaved and said composition is physically and chemically stable to autoclaving.
2. (currently amended) A composition according to claim 1, wherein the pH of the aqueous medium within the liposome composition is ~~about~~ equal to the pK_a of the amino group of the lipophilic amine, and ~~about~~ 50% of the lipophilic amine is protonated in the composition.

3. (currently amended) A composition according to claim 1, wherein the pH of the aqueous medium within the liposome composition is less than the pK_a of the amino group of the lipophilic amine, and a major portion of the lipophilic amine is protonated in the composition.

4. (currently amended) A composition according to claim 1, wherein the aqueous medium within the liposome composition has a pH of ~~about~~ 1 to ~~about~~ 2 pH units below the pK_a of the amino group of the lipophilic amine.

5. (currently amended) A composition according to claim 1, wherein the pH of the aqueous medium within the liposome composition is between ~~about~~ 4 and the pK_a of the amino group of the lipophilic amine.

6. (currently amended) A composition according to claim 1 wherein the aqueous medium within the liposome composition has a pH of between ~~about~~ 4 and ~~about~~ 8.

7. (currently amended) A composition according to claim 6, wherein the aqueous medium within the liposome composition has a pH of between ~~about~~ 4 to ~~about~~ 7.

8. (currently amended) A composition according to claim 6, wherein the aqueous medium within the liposome composition has a pH of between ~~about~~ 4.5 and ~~about~~ 6.5.

9. (currently amended) A composition according to claim 6, wherein the aqueous medium within the liposome composition has a pH of between ~~about~~ 5 and ~~about~~ 6.

10. (original) A composition according to claim 1, further comprising cholesterol.
11. (original) A composition according to claim 1, further comprising ethanol.
12. (currently amended) A composition according to claim 11, wherein the ethanol is present at between ~~about~~ 2.5% and ~~about~~ 10% of the total volume of the liposome composition.
13. (currently amended) A composition according to claim 1, wherein the phospholipid has a net neutral charge at ~~about~~ physiological pH.
14. (original) A composition of claim 13, wherein the phospholipid comprises phosphatidylcholine.
15. (original) A composition according to claim 1, wherein the aqueous medium is water.
16. (original) A composition according to claim 1, wherein the pharmaceutical agent is also free in the aqueous medium.
17. (currently amended) A composition according to claim 16, wherein the percent of liposome encapsulated pharmaceutical agent comprises ~~about~~ 50% to ~~about~~ 90% of the total amount of pharmaceutical agent present in the liposome composition.
18. (currently amended) A composition according to claim 17, wherein the percent of liposome encapsulated pharmaceutical agent comprises ~~about~~ 60% to ~~about~~ 80% of

the total amount of pharmaceutical agent present in the liposome composition.

19. (currently amended) A composition according to claim 18, wherein the percent of liposome encapsulated pharmaceutical agent comprises ~~about~~ 50% to ~~about~~ 75% of the total amount of pharmaceutical agent present in the liposome composition.

20. (original) A composition according to claim 1, wherein the pharmaceutically acceptable acid of step (b) (i) comprises an organic acid.

21. (original) A composition according to claim 1, wherein the pharmaceutically acceptable acid of step (b) (i) comprises an inorganic acid.

22. (currently amended) A composition according to claim 1, wherein the liposome particles of the liposome composition have a mass median diameter (d(0.5)) of less than ~~about~~ 10 microns.

23. (currently amended) A composition according to claim 22, wherein the liposome particles of the liposome composition have a mass median diameter (d(0.5)) of less than ~~about~~ 6 microns.

24. (original) A composition according to claim 22, wherein the liposome particles of the liposome composition have a mass median diameter (d(0.5)) of less than 4 microns.

25. (currently amended) A composition according to claim 22, wherein the liposome particles of the liposome composition have a mass median diameter (d(0.5)) of less

than ~~about~~ 2 microns.

26. (currently amended) A composition according to claim 1, wherein the lipophilic amine comprises a lipophilic amine that has a log P value of greater than ~~about~~ 1.0 at physiological pH.

27. (currently amended) A composition according to claim 26, wherein the lipophilic amine has a log P value of between ~~about~~ 2 and ~~about~~ 5 at physiological pH.

28. (currently amended) A composition of claim 1, wherein the ratio of pharmaceutical agent to phospholipid is ~~about~~ between 1:100 and ~~about~~ 1:10 mol/mol.

29. (currently amended) A composition of claim 1, wherein the amount of phospholipid present is ~~about~~ 1.5 mM or more in the composition.

30. (currently amended) A composition according to claim 1, wherein upon centrifugation at a g-force of ~~about~~ between ~~about~~ 1000 and ~~about~~ 5000, ~~a temperature of about~~ and a time period of ~~about~~ 2 hours, the ratio of the particle size distribution of the liposomes of the liposome composition after centrifugation relative to that prior to centrifugation is equal to or greater than ~~about~~ 0.6.

31. (canceled)

32. (currently amended) A composition according to claim 1, wherein the liposome composition is autoclaved and said composition is physically and chemically stable

to autoclaving ~~at a temperature of about~~ for a minimum of ~~about~~ 15 minutes.

33. (currently amended) A composition according to claim 31, wherein the liposome compositions are physically and chemically stable for at least ~~about~~ one year at a temperature above the freezing point of the liposome compositions.

34. (original) A composition according to claim 31, wherein the liposome compositions are physically and chemically stable for at least 18 months at a temperature above the freezing point of the liposome compositions.

35. (original) A composition according to claim 31, wherein the liposome compositions are physically and chemically stable for at least 24 months at a temperature above the freezing point of the liposome compositions.

36. (original) A composition according to claim 31, wherein the percent encapsulation of drug in the liposome composition is substantially stable over a period of at least 20 months under an inert atmosphere.

37. (currently amended) A composition according to claim 31, wherein the amount of phospholipid does not chemically degrade by more than ~~about~~ 10% (weight/weight) over a period of at least 20 months.

38. (currently amended) A composition according to claim 31, wherein the amount of phospholipid does not chemically degrade by more than ~~about~~ 5% over a period of at least 20 months.

39. (currently amended) A composition according to claim 31, wherein the lipophilic amine does not chemically degrade by more than ~~about~~ 5% over a period of at least 20 months.

40. (currently amended) A composition according to claim 31, wherein the lipophilic amine does not chemically degrade by more than ~~about~~ 2% (weight/weight) over a period of at least 20 months.

41. (currently amended) A sterile and stable liposome composition for delivering a pharmaceutical agent, the composition comprising: (a) a suitable aqueous medium; (a) liposomes formed from a suitable phospholipid; (b) at least one pharmaceutical agent being at least partially encapsulated in the liposomes, and being selected from: (i) a lipophilic amine and a pharmaceutically acceptable acid, wherein the pharmaceutically acceptable acid is selected from an organic or inorganic acid, and (ii) a pharmaceutically acceptable organic acid salt of a lipophilic amine, and optionally a pharmaceutically acceptable organic acid, and optionally a pharmaceutically acceptable acid comprising a pharmaceutically acceptable organic acid; wherein the composition is autoclaved, and wherein quantity of the pharmaceutically acceptable acid present in the composition is such that the pH of the aqueous medium within the liposome composition is less than or ~~approximately~~ equal to the pK_a of the amino group of the pharmaceutically active lipophilic amine.

42. (currently amended) A sterile and stable composition according to claim 41, wherein the pH of the aqueous medium within the liposome composition is about equal to the pK_a of the amino group of the lipophilic amine, and ~~about~~ 50% of the lipophilic amine is protonated in the composition.

43. (currently amended) A sterile and stable composition according to claim 41, wherein the pH of the aqueous medium within the liposome composition is less than the pK_a of the amino group of the lipophilic amine, and a major portion of the lipophilic amine is protonated in the composition.

44. (currently amended) A sterile and stable composition according to claim 41, wherein the aqueous medium within the composition has a pH of ~~about~~ 1 to ~~about~~ 2 pH units below the pK_a of the amino group of the lipophilic amine.

45. (currently amended) A sterile and stable composition according to claim 41, wherein the pH of the aqueous medium within the liposome composition is between ~~about~~ 4 and the pK_a of the amino group of the lipophilic amine.

46. (currently amended) A sterile and stable composition according to claim 41, wherein the aqueous medium within the composition has a pH of between ~~about~~ 4 and ~~about~~ 8.

47. (currently amended) A sterile and stable composition according to claim 46, wherein the aqueous medium within the composition has a pH of between ~~about~~ 4 to ~~about~~ 7.

48. (currently amended) A sterile and stable composition according to claim 47, wherein the aqueous medium within the composition has a pH of between ~~about~~ 4.5 and ~~about~~ 6.5.

49. (currently amended) A sterile and stable composition according to claim 48, wherein the aqueous medium within the composition has a pH of between ~~about~~ 5 and ~~about~~ 6.

50. (original) A sterile and stable composition according to claim 41, further comprising cholesterol.

51. (original) A sterile and stable composition according to claim 41, further comprising ethanol.

52. (currently amended) A sterile and stable composition according to claim 51, wherein the ethanol is present at between ~~about~~ 2.5% and ~~about~~ 10% of the total volume of the liposome composition.

53. (currently amended) A sterile and stable composition according to claim 41, wherein the phospholipid has a net neutral charge at ~~about~~ physiological pH.

54. (original) A sterile and stable composition according to claim 53, wherein the phospholipid comprises phosphatidylcholine.

55. (original) A sterile and stable composition according to claim 41, wherein the aqueous medium is water.

56. (original) A sterile and stable composition according to claim 41, wherein the pharmaceutical agent is also free in the aqueous medium.

57. (currently amended) A sterile and stable composition according to claim 56, wherein the percent of liposome encapsulated pharmaceutical agent comprises ~~about~~ 50% to ~~about~~ 90% of the total amount of pharmaceutical agent present in the liposome compositions.

58. (currently amended) A sterile and stable composition according to claim 57, wherein the percent of liposome encapsulated pharmaceutical agent comprises ~~about~~ 60% to ~~about~~ 80% of the total amount of pharmaceutical agent present in the liposome compositions.

59. (currently amended) A sterile and stable composition according to claim 58, wherein the percent of liposome encapsulated pharmaceutical agent comprises ~~about~~ 50% to ~~about~~ 75% of the total amount of pharmaceutical agent present in the liposome composition.

60. (original) A sterile and stable composition according to claim 41, wherein the pharmaceutically acceptable acid of step b (i) comprises an organic acid.

61. (original) A sterile and stable composition according to claim 41, wherein the pharmaceutically acceptable acid of step b (i) comprises an inorganic acid.

62. (currently amended) A sterile and stable composition according to claim 41, wherein the liposome particles of the liposome composition have a mass median diameter (d(0.5)) of less than ~~about~~ 10 microns.

63. (currently amended) A sterile and stable composition according to claim 62, wherein the liposomes have a mass median diameter (d(0.5)) of less than ~~about~~ 6 microns.

64. (original) A sterile and stable composition according to claim 63, wherein the liposomes have a mass median diameter (d(0.5)) of less than 4 microns.

65. (currently amended) A sterile and stable composition according to claim 64, wherein the liposomes have a mass median diameter (d(0.5)) of less than ~~about~~ 2 microns.

66. (currently amended) A sterile and stable composition according to claim 41, wherein the liposome compositions are physically and chemically stable and sterile for at least ~~about~~ one year at a temperature above the freezing point of the liposome compositions.

67. (original) A sterile and stable composition according to claim 66, wherein the liposome compositions are physically and chemically stable and sterile for at least 18 months at a temperature above the freezing point of the liposome compositions.

68. (original) A sterile and stable composition according to claim 67, wherein the liposome compositions are physically and chemically stable and sterile for at least 24 months at a temperature above the freezing point of the liposome compositions.

69. (currently amended) A sterile and stable composition according to claim 41, wherein the lipophilic amine comprises a lipophilic amine that has a log P value of

greater than ~~about~~ 1.0 at physiological pH.

70. (currently amended) A sterile and stable composition according to claim 41, wherein the lipophilic amine has a log P value of between ~~about~~ 2 and ~~about~~ 5 at physiological pH.

71. (currently amended) A sterile and stable composition according to claim 41, wherein the ratio of pharmaceutical agent to phospholipid is between ~~about~~ 1:100 and 1:10 mol/mol.

72. (currently amended) A sterile and stable composition according to claim 41, wherein the amount of phospholipids present is ~~about~~ 1.5 mM or more in the composition.

73. (currently amended) A sterile and stable composition according to claim 41, wherein the percent encapsulation of drug in the liposome composition is ~~substantially~~ stable over a period of at least 20 months.

74. (currently amended) A sterile and stable composition according to claim 41, wherein the compositions are ~~substantially~~ chemically stable over a period of at least 20 months.

75. (currently amended) A sterile and stable composition according to claim 41, wherein the amount of phospholipid does not decrease due to chemical degradation by more than ~~about~~ 10% (weight/weight) over a period of at least 20 months.

76. (currently amended) A sterile and stable composition according to claim 41, wherein the amount of phospholipid does not decrease due to chemical degradation by more than ~~about~~ 5% over a period of at least 20 months.

77. (currently amended) A sterile and stable composition according to claim 41, wherein the lipophilic amine does not chemically degrade by more than ~~about~~ 5% (weight/weight) over a period of at least 20 months.

78. (currently amended) A sterile and stable composition according to claim 41, wherein the lipophilic amine does not chemically degrade by more than ~~about~~ 2% over a period of at least 20 months.

79. (withdrawn) A method for producing a stable liposome composition for delivering a pharmaceutical agent, the method comprising the steps of: (a) providing a suitable aqueous medium; (b) providing a suitable phospholipid; (c) providing at least one pharmaceutical agent being capable of being at least partially encapsulated in the liposomes, and being selected from: (i) a lipophilic amine and a pharmaceutically acceptable acid, wherein the pharmaceutically acceptable acid is selected from an organic or inorganic acid, and (ii) a pharmaceutically acceptable organic acid salt of a lipophilic amine, and optionally a pharmaceutically acceptable acid comprising a pharmaceutically acceptable organic acid; wherein the quantity of the pharmaceutically acceptable acid present in the composition is such that the pH of the liposome composition is less than or approximately equal to the $pK_{sub.a}$ of the amino group of the pharmaceutically active lipophilic amine; (d) combining the aqueous medium, phospholipid and pharmaceutical agent to form the liposome composition; and (e) optionally autoclaving said composition.

80. (withdrawn) The method according to claim 79, wherein the liposome composition is autoclaved, and wherein the composition is a sterile composition.

81. (withdrawn) The method according to claim 79, wherein the pH of the liposome composition is about equal to the pK.sub.a of the amino group of the lipophilic amine, and about 50% of the lipophilic amine is protonated in the composition.

82. (withdrawn) The method according to claim 79, wherein the pH of the liposome composition is less than the pK.sub.a of the amino group of the lipophilic amine, and a major portion of the lipophilic amine is protonated in the composition.

83. (withdrawn) The method according to claim 79, wherein the composition has a pH of about 1 to about 2 pH units below the pK.sub.a of the amino group of the lipophilic amine.

84. (withdrawn) The method according to claim 79 wherein the pH of the liposome composition is between about 4 and the pK.sub.a of the amino group of the lipophilic amine.

85. (withdrawn) The method according to claim 79, wherein the composition has a pH of between about 4 and about 8.

86. (withdrawn) The method according to claim 79, wherein the composition has a pH of between about 4 to about 7.

87. (withdrawn) The method according to claim 79, wherein the composition has a pH of between about 4.5 and about 6.5.

88. (withdrawn) The method according to claim 79, wherein the composition has a pH of between about 5 and about 6.

89. (withdrawn) The method according to claim 79 wherein at least one of cholesterol and ethanol is further provided, and step (d) comprises the step of combining the aqueous medium, phospholipids, pharmaceutical agent, and the at least one of cholesterol and ethanol to form the liposome compositions.

90. (withdrawn) The method according to claim 89, wherein ethanol is present at between about 2.5% and about 10% of the total volume of the liposome composition.

91. (withdrawn) The method according to claim 79, wherein the phospholipid has a net neutral charge at about physiological pH.

92. (withdrawn) The method according to claim 79, wherein the phospholipid comprises phosphatidylcholine.

93. (withdrawn) The method according to claim 79, wherein the aqueous medium is water.

94. (withdrawn) The method according to claim 79, wherein the pharmaceutical agent is also free in the aqueous medium.

95. (withdrawn) The method according to claim 79, wherein the percent of liposome encapsulated pharmaceutical agent comprises about 50% to about 90% of the total amount of pharmaceutical agent present in the liposome composition.

96. (withdrawn) The method according to claim 79, wherein the percent of liposome encapsulated pharmaceutical agent comprises about 60% to about 80% of the total amount of pharmaceutical agent present in the liposome composition.

97. (withdrawn) The method according to claim 79, wherein the percent of liposome encapsulated pharmaceutical agent comprises about 50% to about 75% of the total amount of pharmaceutical agent present in the liposome composition.

98. (withdrawn) The method according to claim 79, wherein the pharmaceutically acceptable acid of step c (i) comprises an organic acid.

99. (withdrawn) The method according to claim 79 wherein the pharmaceutically acceptable acid of step c (i) comprises an inorganic acid.

100. (withdrawn) The method according to claim 79, wherein the liposome particles of the liposome composition have a mass median diameter ($d(0.5)$) of less than about 10 microns.

101. (withdrawn) The method according to claim 100, wherein the liposome particles of the liposome composition have a mass median diameter ($d(0.5)$) of less than about 6 microns.

102. (withdrawn) The method according to claim 100, wherein the liposomes have a mass median diameter (d(0.5)) of less than 4 microns.

103. (withdrawn) The method according to claim 100, wherein the liposomes have a mass median diameter (d(0.5)) of less than about 2 microns.

104. (withdrawn) The method according to claim 79, wherein the liposome compositions are physically and chemically stable and sterile for at least about one year at a temperature above the freezing point of the liposome compositions.

105. (withdrawn) The method according to claim 79, wherein the liposome compositions are physically and chemically stable and sterile for at least 18 months at a temperature above the freezing point of the liposome compositions.

106. (withdrawn) The method according to claim 79, wherein the liposome compositions are physically and chemically stable and sterile for at least 24 months at a temperature above the freezing point of the liposome compositions.

107. (withdrawn) The method according to claim 79, wherein the lipophilic amine comprises a lipophilic amine that has a log P value of greater than about 1.0 at physiological pH.

108. (withdrawn) The method according to claim 79, wherein the lipophilic amine has a log P value of between about 2 and about 5 at physiological pH.

109. (withdrawn) The method according to claim 79, wherein the ratio of

pharmaceutical agent to phospholipid is about between 1:100 and 1:10 mol/mol.

110. (withdrawn) The method according to claim 80, wherein the amount of phospholipids present is about 1.5 mM or more in the composition.

111. (withdrawn) The method according to claim 80, wherein the percent encapsulation of drug in the liposome composition is substantially stable over a period of at least 20 months.

112. (withdrawn) The method according to claim 80, wherein the compositions are substantially chemically stable over a period of at least 20 months.

113. (withdrawn) The method according to claim 80, wherein the amount of phospholipid does not decrease due to chemical hydrolysis or oxidation by more than about 10% (weight/weight) over a period of at least 20 months.

114. (withdrawn) The method according to claim 80, wherein the amount of phospholipid does not decrease due to chemical hydrolysis or oxidation by more than about 5% (weight/weight) over a period of at least 20 months.

115. (withdrawn) The method according to claim 80, wherein the lipophilic amine does not chemically degrade by more than about 5% (weight/weight) over a period of at least 20 months.

116. (withdrawn) The method according to claim 80, wherein the lipophilic amine does not chemically degrade by more than about 2% over a period of at least 20

months.

117. (currently amended) A sterile and stable liposome composition according to claim 41, exhibiting one or more of the following characteristics over a period of at least one year upon autoclaving and storage at a temperature above the freezing point of the composition: (i) a change in percent encapsulation of no more than ~~about~~ 5%; (ii) a change in phospholipid concentration of no more than ~~about~~ 10% by weight (iii) a change in concentration of lipophilic amine due to chemical hydrolysis and/or oxidation of no more than ~~about~~ 5% by weight; (iv) a lack of formation of visible aggregates; (v) a change in the mass median diameter of no more than ~~about~~ 10% as determined optically.

118. (currently amended) A stable liposome composition of claim 1, when prepared by a method for producing a stable liposome composition for delivering a pharmaceutical agent, the method comprising the steps of: (a) providing a suitable aqueous medium; (b) providing a suitable phospholipid; (c) providing at least one pharmaceutical agent being capable of being at least partially encapsulated in the liposomes, and being selected from: (i) a lipophilic amine and a pharmaceutically acceptable acid, wherein the pharmaceutically acceptable acid is selected from an organic or inorganic acid, and (ii) a pharmaceutically acceptable organic acid salt of a lipophilic amine, and optionally a pharmaceutically acceptable acid comprising a pharmaceutically acceptable organic acid; wherein the quantity of the pharmaceutically acceptable acid present in the composition is such that the pH of the aqueous medium within the liposome composition is less than or ~~approximately~~ equal to the pK_a of the amino group of the pharmaceutically active lipophilic amine; (d) combining the aqueous medium, phospholipid and pharmaceutical agent to form

the liposome composition; and (e) optionally autoclaving said composition.

119. (currently amended) A sterile and stable liposome composition of claim 41, when prepared by a method for producing a stable liposome composition for delivering a pharmaceutical agent, the method comprising the steps of: (a) providing a suitable aqueous medium; (b) providing a suitable phospholipid; (c) providing at least one pharmaceutical agent being capable of being at least partially encapsulated in the liposomes, and being selected from: (i) a lipophilic amine and a pharmaceutically acceptable acid, wherein the pharmaceutically acceptable acid is selected from an organic or inorganic acid, and (ii) a pharmaceutically acceptable organic acid salt of a lipophilic amine, and optionally a pharmaceutically acceptable acid comprising a pharmaceutically acceptable organic acid; wherein the quantity of the pharmaceutically acceptable acid present in the composition is such that the pH of the aqueous medium within the liposome composition is less than or approximately equal to the pK_a of the amino group of the pharmaceutically active lipophilic amine; (d) combining the aqueous medium, phospholipid and pharmaceutical agent to form the liposome composition; and (e) optionally autoclaving said composition; wherein the liposome composition is autoclaved, and wherein the composition is a sterile composition.

120. (original) A pharmaceutical composition comprising a liposomal composition according to claim 1.

121. (withdrawn) The use of a liposome composition according to claim 1, as a medicament.

122. (withdrawn) The use according to claim 121, wherein the medicament is administered via inhalation through the pulmonary system, topically, or parenterally.

123. (withdrawn) The use according to claim 122, wherein the topical medicament is suitable for ophthalmic administration.

124. (withdrawn) The use according to claim 122, wherein the medicament is suitable for pulmonary administration.

125. (withdrawn) A device for containing a stable liposome composition as claimed in claim 1 and being droplets for inhalation of the composition by a patient.

126. (withdrawn) A kit for delivery of a pharmaceutical agent to a patient, the kit comprising instructions for use, a device containing a stable liposome composition as claimed in claim 1 and being capable of generating aerosol droplets of the composition for inhalation by a patient.

127. (withdrawn) A method of increasing the stability of liposome compositions, said method comprising the steps of: (a) providing a suitable aqueous medium; (b) providing a suitable phospholipid; (c) providing at least one pharmaceutical agent being capable of being at least partially encapsulated in the liposomes, and being selected from: (i) a lipophilic amine and a pharmaceutically acceptable acid, wherein the pharmaceutically acceptable acid is selected from an organic or inorganic acid, and (ii) a pharmaceutically acceptable organic acid salt of a lipophilic amine, and optionally a pharmaceutically acceptable organic acid; wherein quantity of the

pharmaceutically acceptable acid present in the composition is such that the pH of the liposome composition is less than or approximately equal to the pK_a of the amino group of the pharmaceutically active lipophilic amine; (d) combining the aqueous medium, phospholipid and pharmaceutical agent to form the liposome composition; and (e) autoclaving said liposome composition at conditions effective to sterilize said compositions, thereby affording compositions with increased stability relative to the stability of the composition prior to autoclaving.

128. (withdrawn) The method according to claim 127, wherein the step of autoclaving is carried out at a temperature of about 121°C for a minimum of about 15 minutes under an inert atmosphere.

129. (withdrawn) The method of claim 128, wherein the inert atmosphere during autoclaving comprises argon or nitrogen.

130. (withdrawn) A method of identifying a phase stable liposome composition, the method comprising the steps of: (a) providing a liposome composition comprising a phospholipid, an aqueous solution, a pharmaceutical agent, and optionally ethanol and a sterol, (b) optically determining the mass median diameter ($d(0.5)$) value of the liposome composition; (c) centrifuging the liposome composition at between about and about at about for about 2 hours; (d) optically determining the mass median diameter ($d(0.5)$) value of the supernatant portion of the liposome composition solution after centrifugation step (c); (e) calculating the ratio of the mass median diameter ($d(0.5)$) particle size distribution value of the solution after centrifugation to that of the solution prior to centrifugation; wherein a phase stable liposome composition is identified as such if the composition has a ratio in step (e) of

about 0.6 or greater.

131. (withdrawn) A method of claim 130, wherein the phase stable liposome composition is identified as such if the composition has a ratio in step (e) of about 0. or greater.

132. (withdrawn) A method of claim 130, wherein prior to centrifugation the composition is autoclaved.